



INVESTOR IN PEOPLE

The Patent Office
 Concept House
 Cardiff Road
 Newport
 South Wales
 NP10 8QQ

REC'D 19 NOV 2004

WIPO PCT

BEST AVAILABLE COPY

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated 3 November 2004

**PRIORITY
 DOCUMENT**

SUBMITTED OR TRANSMITTED IN
 COMPLIANCE WITH RULE 17.1(a) OR (b)

Patents Form 1/77

Patents Act 1977
(Rule 16)The
Patent
Office28OCT03 E847892-1 002835
P01/7700 0.00-0325141.0

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form.)

THE PATENT OFFICE
JR
28 OCT 2003
RECEIVED BY FAX
WMO/P200504

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

2. Patent application number
(The Patent Office will fill in this part)

0325141.0

28 OCT 2003

3. Full name, address and postcode of the or of
each applicant (underline all surnames)

Xiros PLC, 30 Blenheim Terrace, Leeds, LS2 9HD

Patents ADP number (if you know it)

If the applicant is a corporate body, give the
country/state of its incorporation

4. Title of the invention

Repair of damaged tissue on a bone site

5. Name of your agent (if you have one)

Urquhart-Dykes & Lord

"Address for service" in the United Kingdom
to which all correspondence should be sent
(including the postcode)Tower North Central
Merrion Way
Leeds LS2 8PA
United Kingdom

Patents ADP number (if you know it)

1644004 ✓

6. If you are declaring priority from one or more
earlier patent applications, give the country
and the date of filing of the or of each of these
earlier applications and (if you know it) the or
each application number

Country

Priority application number
(if you know it)Date of filing
(day / month / year)7. If this application is divided or otherwise
derived from an earlier UK application,
give the number and the filing date of
the earlier application.

Number of earlier application

Date of filing
(day / month / year)8. Is a statement of inventorship and of right
to grant of a patent required in support of
this request? (Answer 'Yes' if)

YES

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an
applicant, orc) any named applicant is a corporate body.
See note (d))

Patents Form 1/77

0084104 28-Oct-03 04:29

20/10 00 17:10 FAX 0113 245 0420

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 16

Claim(s)

Abstract

Drawing(s) 10

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

18-10-03

12. Name and daytime telephone number of person to contact in the United Kingdom

W M Orr - 0113 245 2388

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- b) Write your answers in capital letters using black ink or you may type them.
- c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- e) Once you have filled in the form you must remember to sign and date it.
- f) For details of the fee and ways to pay please contact the Patent Office.

Patents Form 1/77

0084104 28-Oct-03 04:29

-1-

CASE 1

REPAIR OF DAMAGED TISSUE ON A BONE SITE

This invention relates generally to repair of damaged tissue on a bone site, and which includes bone sites on animals and humans.

- 5 The invention has been developed primarily, though not exclusively, in connection with the repair of damaged cartilage and the repair of cartilage defects in synovial human or animal joints, and in particular to provide further improvement in the art over the disclosure in WO01/39694.

BACKGROUND OF THE INVENTION

- 10 Reference will be made herein below to the repair of damaged cartilage. It should be understood that the damaged tissue may be other types of tissue including damaged surface bone itself. Reference will also be made herein below to the repair of cartilage of knee joints and again it should be understood that the present invention may be applied to other body joints and indeed to other organs of the body which consist of or incorporate bone.
- 15 Defects in the articular surfaces of the knee joint, especially in young active individuals, are currently a focus of interest by orthopaedic surgeons. It is desirable to repair such defects in order to prevent the articular damage from spreading, thereby leading to serious degenerative changes in the joint. Such changes may result in the need for a total knee replacement which is particularly undesirable in young active individuals with a long life
- 20 expectancy. If the lifetime of the implant is less than that of the patient, a revision

procedure may be necessary. Preferably, such revision procedures are to be avoided, having regard to inconvenience to the patient. Furthermore implant revision procedures are both lengthy and very costly.

5 Various techniques for cartilage repair are either in current use or under development but publicly disclosed. The Osteochondral Autogenous Transplant System (OATS) of Arthrex Inc is perhaps the most widely used method. Osteochondral plugs are harvested from a healthy donor and, more particularly, from a site which is claimed to be 'non-weight-bearing'. These plugs are transplanted into the site of the cartilage defect. This procedure has been applied primarily in the knee joint.

10 However, there are no donor sites in the knee with cartilage of a comparable thickness to that of the deficient site that can be described as 'non-weight-bearing' areas. The solcus terminalis, the most currently used site for harvesting such grafts, is in direct contact with the lateral meniscus at the position of full knee extension, and is therefore a weight-bearing site.

15 Furthermore, harvesting a large osteochondral plug from the solcus terminalis may cause the lateral meniscus to become lax and impair its load-bearing function. As a result, all the tibio-femoral loads would be transmitted onto the small area of direct contact between the femur and tibia. The resultant stresses could be as high as those arising after meniscectomy with its consequential degenerative changes in the cartilage of the tibial plateau. Such
20 changes have always been regarded as precursors to osteo-arthritis.

While the OATS method provides a reasonable technique, including good instrumentation, for transplanting live autogenous grafts for repair of defects in cartilage, it involves introducing potentially damaging effects at other sites with the serious disadvantages discussed above. In addition, harvesting a plug from a donor site creates a new damage in
25 the knee articular surface. For this reason, OATS would not be suitable for the repair of

-3-

large defects. The use of OATS for small repairs would probably limit the magnitude of the problem discussed above, but it would also limit the indication for using this technique.

The technique known as Autogenous Chondrocyte Implants (ACI) of Genzyme Inc is a conceptually elegant approach which is gaining popularity. The procedure is intended for repair of small as well as large irregular defects, and is achieved in two stages. In the first stage, chondrocytes (cartilage cells) are harvested from the patient and cultured in suspension. In the second stage of the operative procedure, cartilage residue is cleared from the repair site. The site is then covered with a piece of periosteal tissue which is sutured to the perimeter of the repair area. The chondrocytes are then injected into the repair site using a hypodermic syringe, puncturing the periosteum with the needle of the syringe. In a variation of this procedure, the periosteal tissue is applied to the repair site in the first stage of the operation to ensure that, by the time the chondrocytes are due to be injected, an adequate seal has formed between the tissue and the perimeter of the cartilage. There is a high probability of the chondrocytes escaping through the hole of the hypodermic needle in either version of the procedure.

A further problem with the second version of the procedure is the probability of tissue adhesions occurring between the periosteal tissue and the bottom of the repair site.

This procedure has a low rate of success and the quality of cartilage in the repair site is questionable. As with the OATS method, this procedure is not minimally invasive. It is also a disadvantage that it requires two operative procedures although the first stage is less invasive as it can be performed arthroscopically.

A procedure proposed by Smith & Nephew involves the production of cartilage discs formed by allograft chondrocyte culture on an absorbable textile fabric. The discs are grown in the laboratory, the allograft chondrocytes being cultured on a matrix of a non-

-4-

woven mesh of a bioabsorbable material, typically polyglycolic acid. When this procedure is completed, the disc is supplied for implantation at the repair site.

5 An advantage of this method is that no damage to an intact healthy chondral site will occur since the method uses allograft sources. Furthermore the procedure is completed in a one stage operation.

The discs can be made in different sizes but there must be a limit to the size of the defect which can be repaired with a loose disc which is merely placed in the repair site. The implant could move freely in the joint. It could wrinkle under the influence of tangential forces and, as a result, could be completely damaged. This problem would be exacerbated
10 by the low compressive modulus of the material.

A further disadvantage with this method is that the material, being an allograft, runs the risk of infection. Although a small risk, this is an inherent problem with any allograft.

A further problem to be anticipated with this type of graft is the compressive modulus of the material. It may be quite small and the material might be in need of conditioning to
15 achieve a modulus compatible with that of cartilage of the surrounding area.

The DePuy cartilage repair system is a hexagonal disc of non-woven fabric made of a bioabsorbable material and which has a hard substrate that enables the implant to be attached to the bone. The hexagonal shape of the disc allows repair of damaged areas of irregular shapes by using a plurality of discs in a close-packed array. The disadvantages
20 with this system are that the use of too many adjacent hexagonal discs will result in much damage to the bone substrate, and, further the technique may require considerable skill and its application may also be time consuming.

-5-

STATEMENTS OF INVENTION

According to one aspect of the invention there is provided a repair kit for use in the repair of damaged cartilage present at or on the surface of a bone site in an animal or human, in which the damaged cartilage is removed from the site and a groove is formed about the site and into the bone prior to implantation of the repair kit, and said repair kit comprising;

5 a pad of bio-compatible material shaped and dimensioned to occupy at least part of the site from which the damaged tissue has been removed;

elongate connecting portions attached to the periphery of the pad in an array corresponding in shape to the groove, said portions being intended to extend away from
10 the general plane of the pad so as to be introduced into the groove and to be anchored therein; and

a retaining element slidable depthwise of the groove in order to anchor at least some of the connecting portions in the groove and thereby locate and retain the pad in said part of the bone site.

15 The elongate connecting portions may be formed by one or more flexible tensile elements taken or "threaded" through the pad, at or near the periphery of the pad, and which can extend generally perpendicular to the plane of the pad so as to be received by the groove with adjacent elements being spaced apart from each other to allow tissue ingrowth to the groove.

20 A single filament, thread or yarn may be attached to the periphery of the pad, and extend downwardly of the pad in loops of generally parallel lengths.

The retaining element may be pre-attached to the ends of the loops, so that downward movement of the retaining element into the groove pulls the loops downwardly until the pad is received by and then anchored in or at the bone site.

Alternatively, the ends of the loop may first be entered into the groove by other means, including use of an introducer tool, and then the retaining element can be forced downwardly of the groove to engage with the loop ends and pull them downwardly to anchored engagement in the groove.

- 5 The retaining element is slidable depthwise of the groove, and may be pre-formed to have a shape corresponding generally with at least part of the shape of the groove, as seen in plan; alternatively, the retaining element may be deformable to take up the required shape, prior to introduction into the groove.

- 10 In the case of a circular groove, which is conveniently formed by use of a cylindrical reamer tool, the retaining element will therefore take up the shape of at least part of the circumference of a circle.

- 15 In a preferred arrangement, the retaining element comprises a ring, or a near complete ring, and which may be "threaded" through, or connected with, the looped ends of the elongate connecting elements, either during the manufacture of the repair kit, or during the implantation procedures.

- 20 The groove can of course take other shapes than circular, including part circular, and the retaining element will correspond in shape to at least part of the shape of the groove. Two or more retaining portions may be provided, to act together in anchoring the looped ends in the groove, but for convenience of implantation it is preferred, wherever possible, that a single retaining element is utilised.

According to a further aspect of invention, a repair kit as defined above and/or preferred features thereof, may be employed in carrying out a method of repair of damaged cartilage tissue at a bone site of an animal or human being.

-7-

According to a third aspect of the present invention there is provided an alternative and improved method of fixation of the general type of device disclosed in WO 01/39694, for the repair of damaged tissue present at or on the surface of bone in an animal, including a human being, the method comprising forming a narrow groove around at least part of said
5 damaged tissue, which groove extends into the bone below the damaged tissue, replacing the tissue around which the groove extends by at least one layer of biocompatible replacement material, and anchoring the material to the bone by the use of retaining means extending from the material into the groove.

Preferably the groove is formed by a reaming device.

10 Preferably the depth of the groove is at least five times that of the thickness of tissue which is replaced. For instance, where the tissue to be replaced is circular, (up to certain limits of diameter), the depth of the groove is preferably at least equal to the diameter of the tissue being replaced.

Preferably the replacement material is in the form of a circular or part circular pad. The
15 material may be bio-absorbable or non-bio-absorbable. It may be seeded with chondrocytes or cartilage-forming cells during surgery.

GENERAL DESCRIPTION OF PREFERRED EMBODIMENTS

The improved device may comprise a pad made of woven or non-woven material, permanent or bioabsorbable when implanted in the body, which is connected to threads
20 made of mono-filamentous or multi-filamentous yarns, or sutures that are of permanent or bioabsorbable materials when implanted in the body, said threads can be connected to the pad through its substance either parallel to the surfaces of the pad or through the substance of the pad in a substantially perpendicular or inclined direction to the surfaces of the pad

-8-

(as illustrated in figure 1 and figure 2), the thread ends (which can be in the form of loops or single ends or both) emerging near the periphery of the pad and projecting from the site where they emerge by a distance of say 30 millimetres but can be longer or shorter, thus forming means of securing the pad in a narrow groove prepared to surround a repair site prepared as described above, and a ring of a matching in shape that of the groove which may not necessarily be circular in shape, such ring is made of a biocompatible metal or any other suitable material, and the ring can be made an integral component or made up of segments; said ring is pushed into the groove trapping the threads between both of its surfaces and the two bony surfaces of the groove thus securing the pad in the repair site.

10 The advantage of the use of threads and retaining rings as per the preferred embodiment, compared with the cover sheet described in the disclosure in WO01/39694 is that the retaining threads do not occupy much space in the annular groove thus allowing bone healing to occur freely within the groove whereas the cover sheet used in the disclosure in WO01/39694 was almost impervious to bone trabeculae that would bridge the space across the groove. Another advantage is that the pad can be substantially of the same diameter as that of the repair site and so the edge of the pad would be in contact with that of the cartilage surrounding the repair site and so expediting the integration of the new tissue with the native cartilage.

20 In a different configuration the ring and pad and threads can be connected so as to form a unitary device that can perform the same function and be fixed in the repair site in the same manner as described.

Multiple pads can be loosely added below the top pad to stack up to the thickness required for the repair of cartilage in the defective site (as shown in Figure 3), but in another configuration (as Figure 4 shows) multiple pads can be connected to the same threads attached to the top pad such that during surgery on determining the number of pads required for the repair some of these pads can be removed leaving the correct number of pads.

-9-

Repair sites are preferably delineated with annular grooves of regular shapes that can easily be generated such as circles (as Figure 5 shows) and so circular pads and circular retaining rings can be used and easily manufactured.

Where repair sites are not possible to encircle with one circular annular groove then the repair can be effected using circular pads and part-circular pads e.g. crescent-shaped pads, the latter are connected to threads in the same manner and retained by portions of rings (as in Figure 8).

Another example for repair of a larger repair site that may be conveniently enclosed by a larger circle may use two pads, a smaller circular pad and a donut shaped pad that can be placed concentrically in the repair site (as in Figure 9). The said repair site would have two concentric grooves made, the larger of which would surround and enclose the extent of the defective site. At least two retaining rings would be used to retain the pads using threads attached to the free circular perimeters of the pads as described earlier. The rings can be separate from or connected to their respective pads so that each pad and retaining ring form a unitary device. This principle of lateral stacking of the pads can be extended to repair sites of large areas and complex shapes.

The following describes an instrument for delivery of the implant device just described in this application, i.e. the implant device comprising the pad(s), retaining ring and connecting threads as a unitary device. More detail is now shown in Figure 10-a concerning a possible configuration of the implant device, and in particular that of the threads connecting the pad to the retaining ring and the geometry of the cross section of the retaining ring. The perspective view of the implant device shows the direction of the connecting threads, which are in two groups perpendicular to each other. The threads are attached to the ring at regularly spaced holes/locating positions. The space on the circumference of the retaining ring between any two adjacent groups of threads is substantially larger than the spacing between any two adjacent points at which the threads are connected to the retaining ring. The vertical view,

-11-

Figure 5 is a schematic illustration of the preparation of a bone site having damaged cartilage, ready for implantation via a repair kit according to the invention;

Figure 6 is an illustration, similar to Figure 5, and showing implantation of a repair kit on the prepared bone site;

5 Figure 7 is a perspective and schematic illustration of a repair kit according to the invention;

Figure 8 (a), (b) and (c) show schematically implantation of a repair kit according to the invention on a bone site, in which two separate adjacent portions of damaged tissue are removed, prior to implantation of a pair of co-operating repair kits corresponding to each of the removed portions of damaged tissue material;

10 Figure 9 illustrates schematically a further example of stacking of pads concentrically for the repair of a larger defect;

Figures 10a and 10b are, respectively, a perspective view of a repair kit according to the invention in more detail, and a section on A-A in Figure 10a; and

15 Figure 11 is a diagrammatic illustration of an introducer tool for implanting the repair kit disclosed herein.

Referring first to Figures 1 and 2 of the drawings, a repair kit according to the invention is designated generally by reference 10 and is intended to be used in the repair of damaged tissue such as cartilage present at or on the surface of a bone site in an animal or human being. Prior to implantation of the repair kit, the damaged tissue is removed from the site, and a groove is formed about the site and into the bone. The order of removal of the damaged tissue and forming of the groove is not specific and either can be done before the other depending on the instruments that the surgeon might choose to employ during the surgery.

25 The repair kit 10 comprises a pad 11 of bio-compatible material shaped and dimensioned to occupy at least part of the site from which the damaged tissue has been removed. The kit also includes elongate connecting portions attached to the periphery of pad 11, and forming an array corresponding in shape to the groove, such portions being intended

to extend away from the general plane of the pad 11, so as to be introduced into the groove and to be anchored therein.

5 In the schematically illustrated embodiment of Figures 1 and 2, the connecting portions are shown by reference 14, which are loops extending downwardly of the pad 11 in the form of generally parallel lengths which are spaced apart from each other circumferentially of the periphery of the pad. The spacing apart of the generally parallel lengths of connecting portions 14 allows ingrowth of bone tissue to occupy the groove after implantation, and over a period of time.

10 The looped connecting portions may be formed by a single filament, thread or length of yarn attached to the periphery of the pad 11, by being "threaded" completely through the pad, as shown at Reference 12, or only partially into the body of the pad as shown by Reference 13. Connecting portions 14 can also be threaded through the pad in the plane of the pad as indicated in Figure 2.

15 To complete the assembly of the repair kit, i.e. to complete the implantation, a retaining element is provided, which is slidable depthwise of the groove in order to anchor at least some of the connecting portions 14 in the groove and thereby locate and retain the pad 11 in the excavated part of the bone site.

20 The retaining element may be pre-attached to the ends of the loops of the connecting portions 14, so that downward movement of the retaining element into the groove pulls the loop downwardly until the pad 11 is received by and then anchored in or at the bone site.

Alternatively, the ends of the loops may first be entered into the groove by other means, including use of an introducer tool, and then the retaining element can be forced downwardly of the groove to engage with the loop ends and pull them downwardly to anchored engagement in the groove.

-13-

The retaining element is slidable depthwise of the groove, and may be pre-formed to have a shape corresponding generally with at least part of the shape of the groove, as seen in plan. Alternatively, the retaining element may be deformable to take up the required shape, prior to introduction into the groove.

5 In the case of a circular groove, which is conveniently formed by use of a cylindrical reamer tool, the retaining element will therefore take up the shape of least part of the circumference of a circle.

Referring now to Figure 5, this is a schematic illustration of the preparation of a bone site having damaged tissue, which in the illustrated example only, is assumed to be cartilage at a bone of a joint. Adjacent portions of bone are shown by reference 20 and 21, and having
10 overlying cartilage 22, and from which damaged cartilage tissue overlying bone section 21 has been removed. Bone section 21 therefore signifies a defective bone site, and from which a circular "plug" of damaged cartilage tissue has been removed, leaving a shallow cylindrical depression 23, extending down to the upper surface 24 of bone section 21. Subsequently or
15 before, a groove 25 is formed about the bone site, i.e. around the periphery of the circular recess 23, then downwardly into the bone section 21 to a required depth.

Conveniently, the cylindrical recess 23, formed after extraction of damaged tissue, is circular, and similarly the groove 25 also is circular being formed by a cylindrical reamer tool. Reference 27 shows a hole drilled in the sub-chondral bone at the defect site, such hole is
20 drilled to encourage bleeding and migration of bone marrow derived cells to the repair site to expedite the generation of cartilage tissue in the repair site.

Figure 6 shows the implantation of a repair kit 10 on the prepared bone site of Figure 5.

It should be understood, however, that other shapes of recess may be formed, to remove

-14-

damaged tissue and similarly other shapes of groove may be formed, to surround the bone site from which damaged tissue material has been removed. A repair kit according to the invention and a method of use thereof, may be employed in such other surgical operations as described.

5 Figures 1 and 2 show the repair kit 10, constituted by pad 11 and the elongate connecting portions 14, but omits illustration of the "retaining element".

Figure 3 shows a stacked assembly of plurality of pads 11 and Figure 4 shows a plurality of pads 11, of which a lowermost pad 11a is removable.

10 Figure 7 shows an embodiment with a plurality of stacked pads 11, and a retaining ring 26 taken through the lower looped ends of the connecting portions 14. The repair kit may be pre-assembled in this form, in which case the introduction of the ring 26 to the mouth of the groove 25, followed by downward displacement of the ring 26 by a suitable tool, will pull the connecting portions 14 downwardly into the groove 25, and thereby locate and then securely place the pad or pads 11 over the extracted bone site, i.e. overlying the exposed surface of bone section 21.

15 The retaining ring 26 may be rigid, and therefore pre-formed to the shape of the groove. Alternatively, the ring 26 may be deformable, preferably resiliently deformable, and conveniently may form a near complete circle, with slightly spaced facing ends, allowing any necessary deformation of the shape of the ring to correspond with the shape of the groove, and then allow downward displacement of the ring.

20 The ring 26 may be formed so as to fit into only part of the groove, in which case a further retaining portion may be provided, so that two retaining portions can act together, being introduced separately, or together, in order to apply downward pulling force to the connecting portions 14 and then anchor them in position.

-15-

Figure 8 shows how two separate extracted discs of damaged tissue may be removed, by drilling downwardly two separate cylindrical recesses, overlapping, followed by formation of surrounding grooves extending downwardly into the underlying bone.

Two adjacent cylindrical recesses 27 and 28 may therefore be formed, and as shown in Figure 8b, a cooperating pair of separate pads 29 and 30 may be provided, of which pad 30 is circular, and pad 29 is crescent shaped. Each pad 29 and 30 has elongate connecting portions 31 and 32, and corresponding partial retaining ring 33 and full or near full retaining ring 34 as shown, to pull the corresponding pad downwardly into position, and then anchor the pad in position. The pads 29 and 30 then cooperate to fill the space made available by extraction of the two cylindrical and overlapping recesses 27 and 28.

Figure 9 illustrates schematically a further example of stacking of pads concentrically for the repair of a larger defect.

Figure 10a and b shows in more detail the construction of a repair kit according to the invention, and in particular the means by which elongate connecting elements, in the form of threads or sutures are connected to the bio-compatible pad, and from which they extend away generally perpendicularly, when installed. The ends of the connecting elements remote from the pad are anchored to a retaining ring, either during factory assembly of the kit, or just prior to implantation. The retaining ring has a step machined in its outer circumference, to engage a delivery tool or device to be described in detail below with reference to Figure 11.

In Figure 11, this is an axial sectional view through the delivery device and the repair kit or implant device described above. The delivery device (introducer tool) as illustrated, is a one piece tool, which can be used to implant the bio-compatible pad(s) on a prepared bone site, and with the elongate connecting elements and the anchor (ring) being received by the groove which is formed in the bone around the prepared bone site.

The repair kit/implant device may be assembled with the tool just prior to implantation, or they may be assembled together in a "clean room" or other mass-production area, and then supplied in sealed form ready for use by the surgeon.

CASE 1 (Figs 1 to 10)

~~#10~~ ~~#9~~
11/10

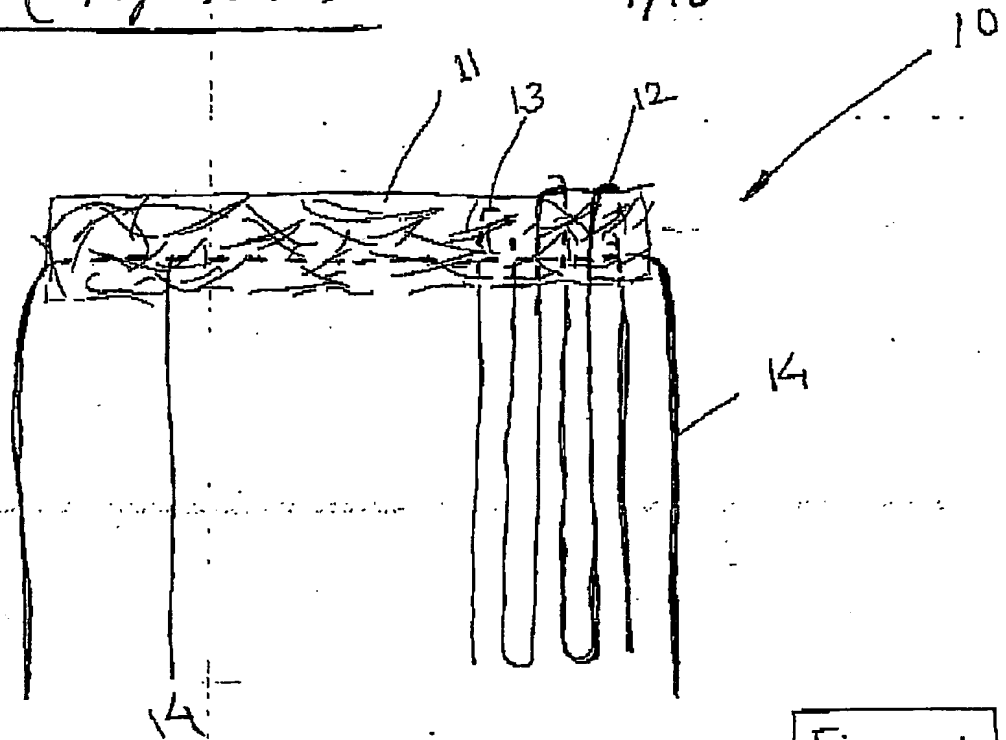


Figure 1

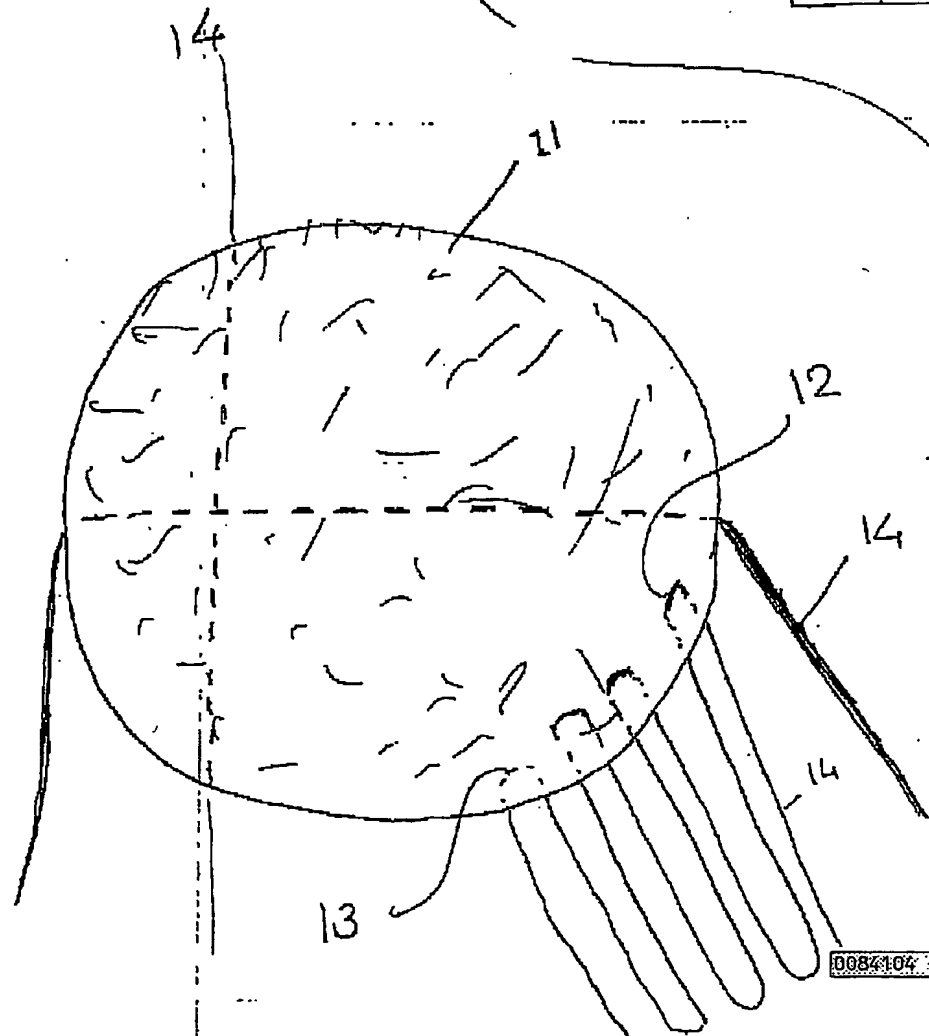


Figure 2

2/10/03

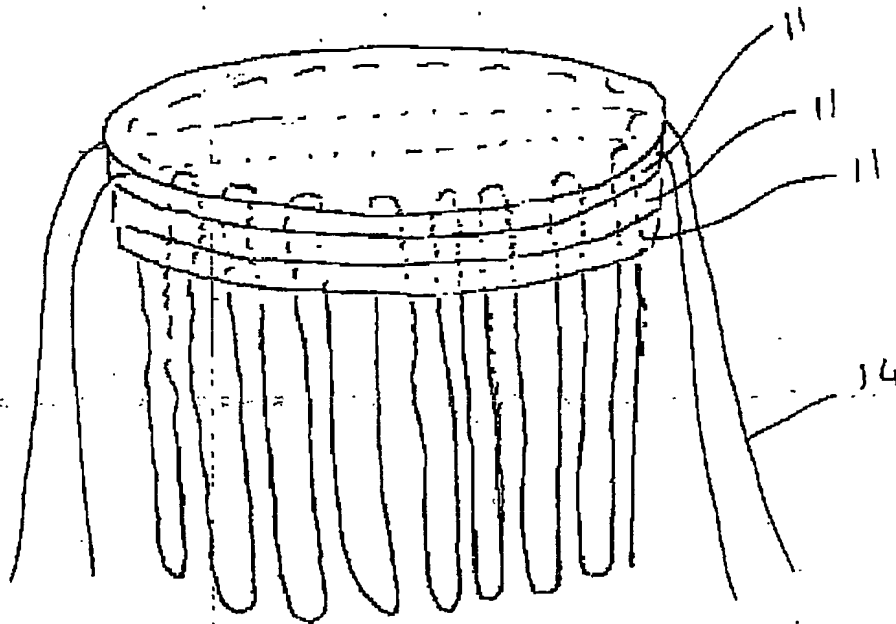


Figure 3

3/10/0

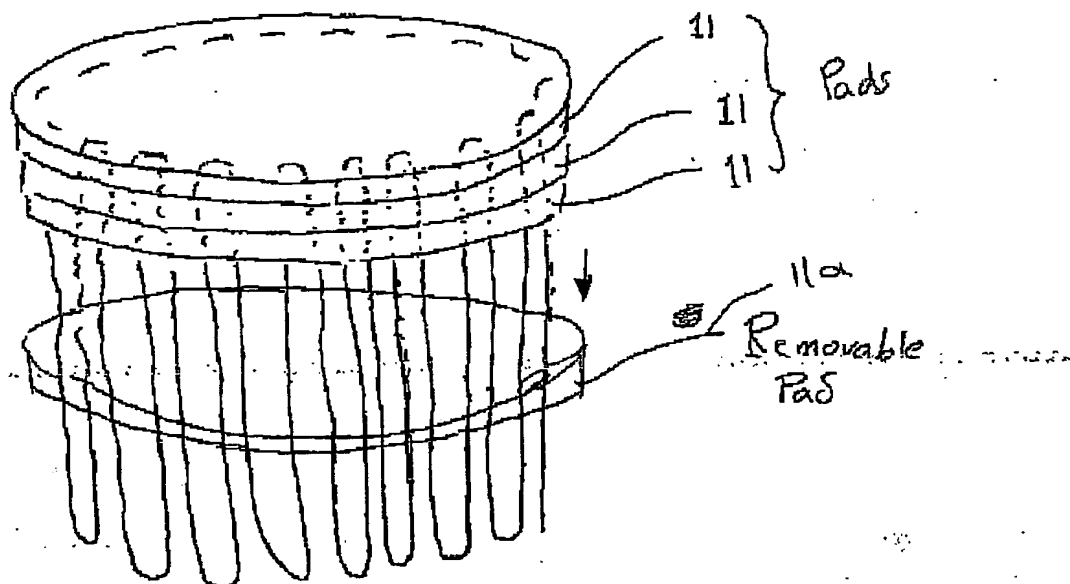
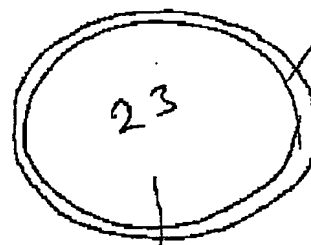
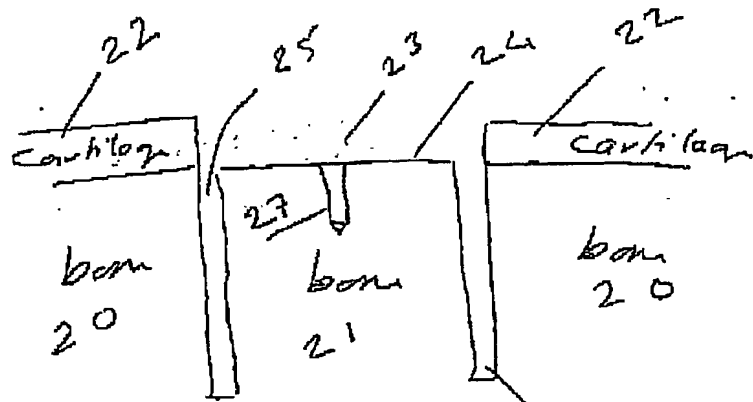


Figure 4

4/10/10



annular groove

Defect site

Figure 5

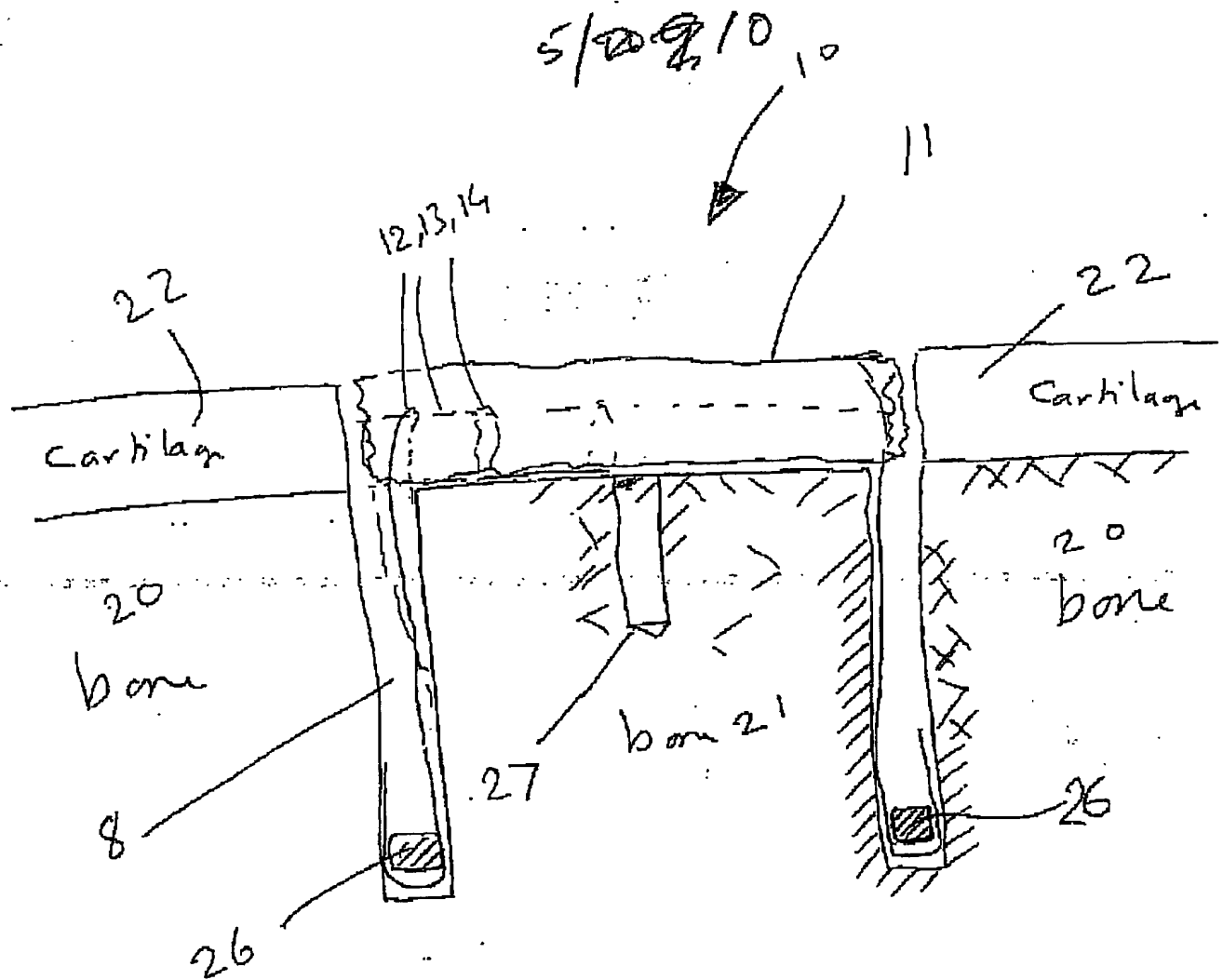


Figure 5

The device in place within a repair site

1 Pad

2,3,4 threads as shown in figure 1

6 retaining ring for retaining threads connected to Pad (or pads) as in figures 1, 2, 3 and 4

7 hole drilled in subchondral bone in the defect site

6/209 10

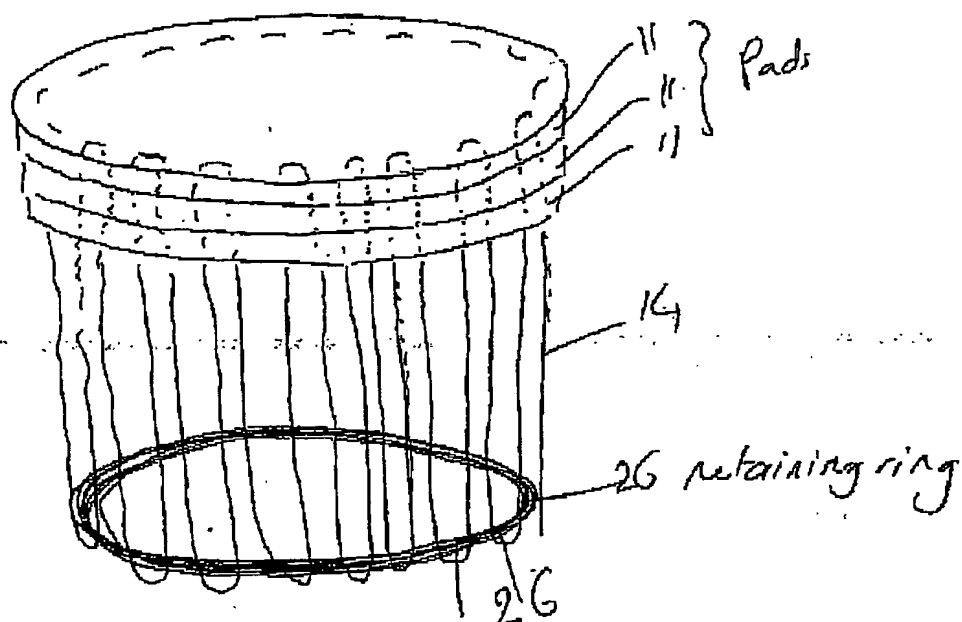


Figure 7

7/209/10

(a)

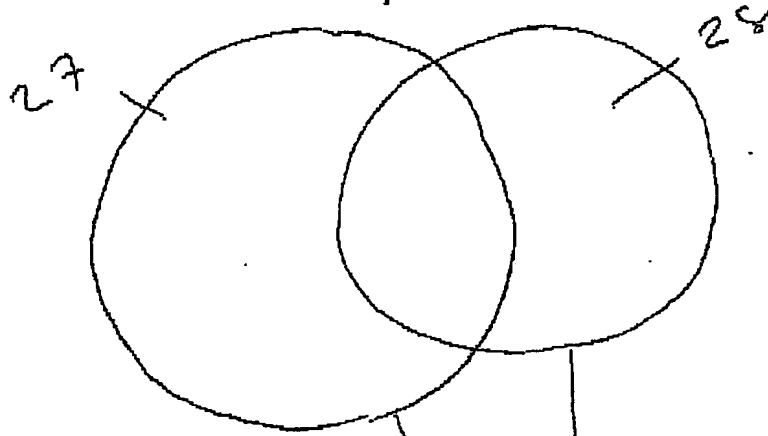
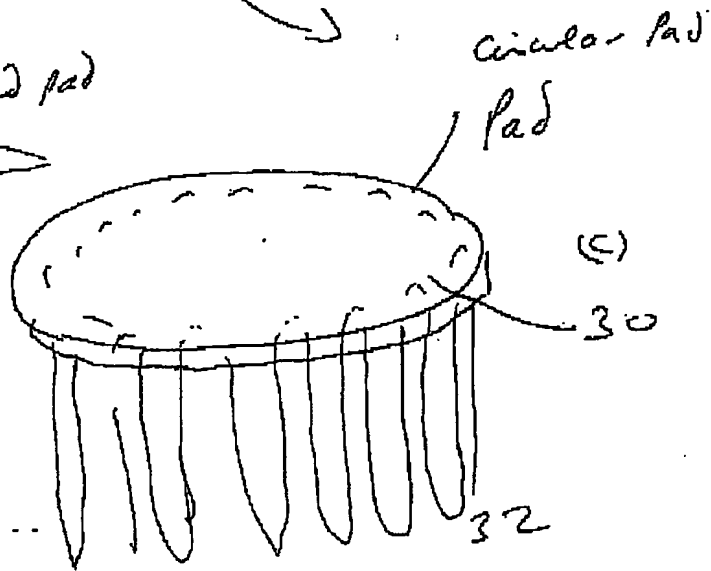
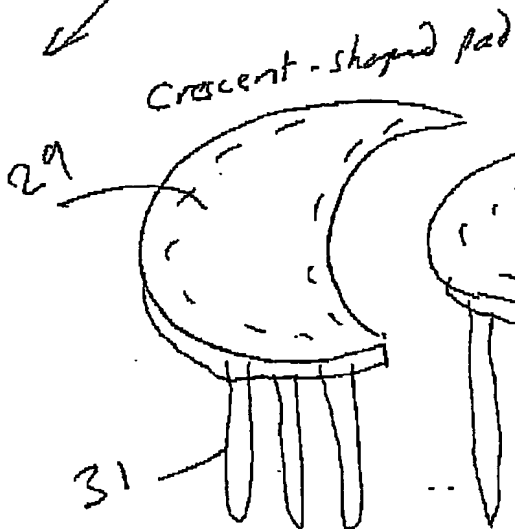


Figure 8

Two annular grooves containing the defect site
Device in two components as in
(b) & (c) - retained by full
ring and a partial ring as in
(d) & (e)

(b)

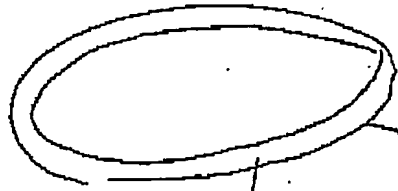


(d)



partial ring to retain crescent pad

(e)



full ring to retain circular pad...

8/10

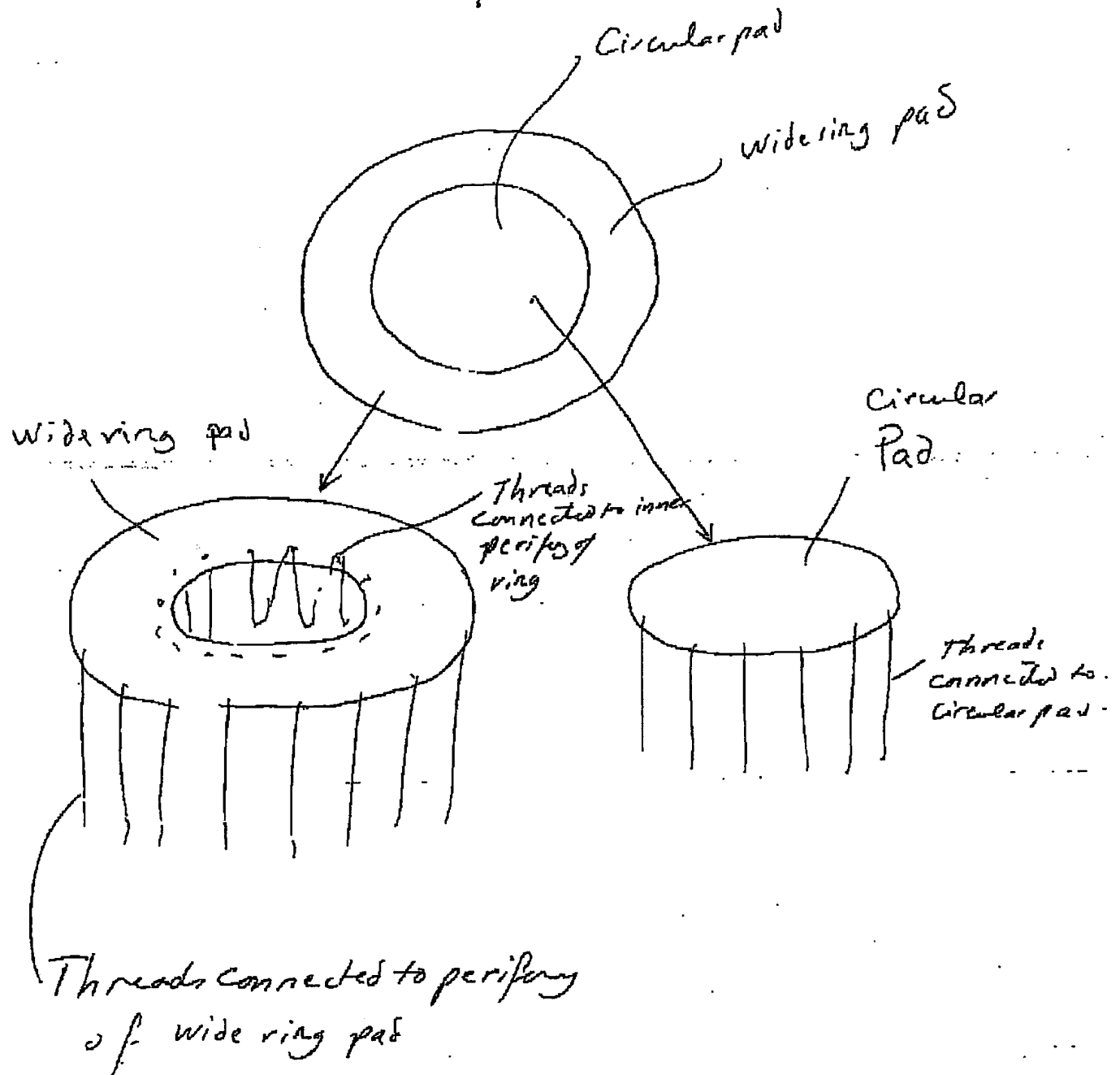


Figure 9

9/9/10

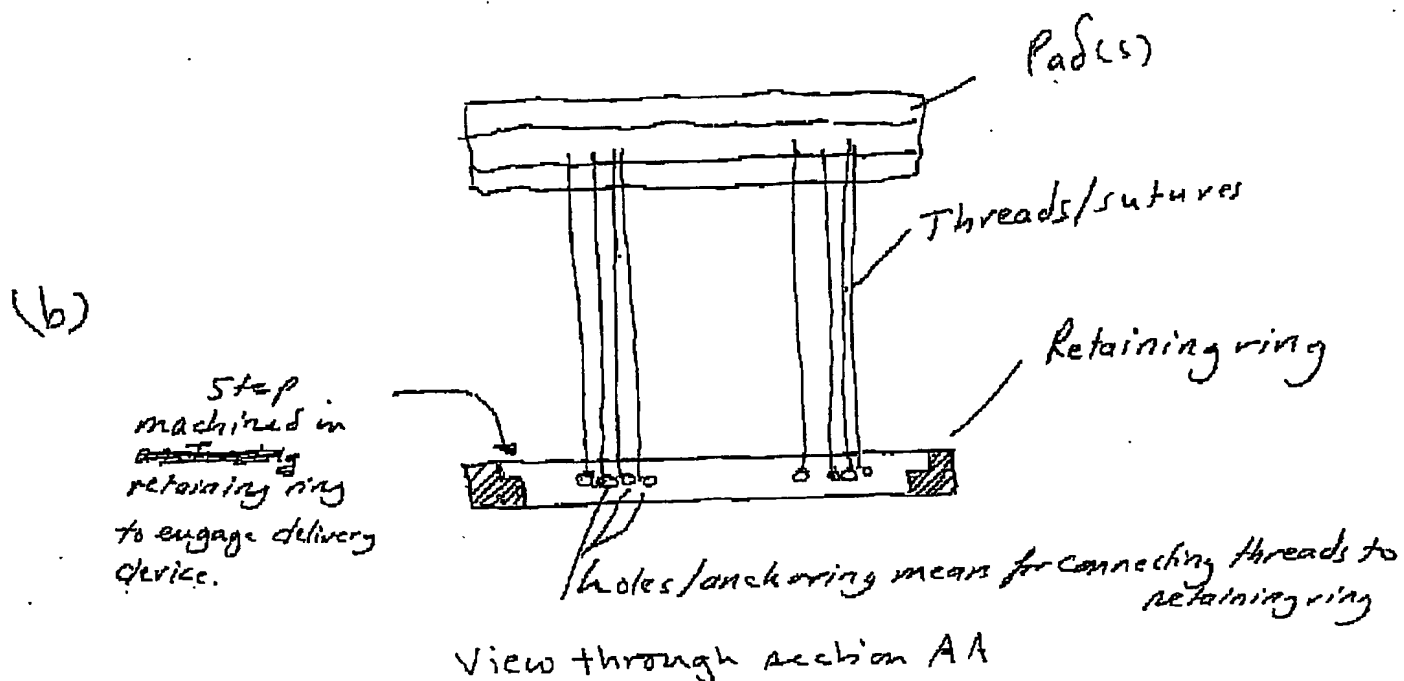
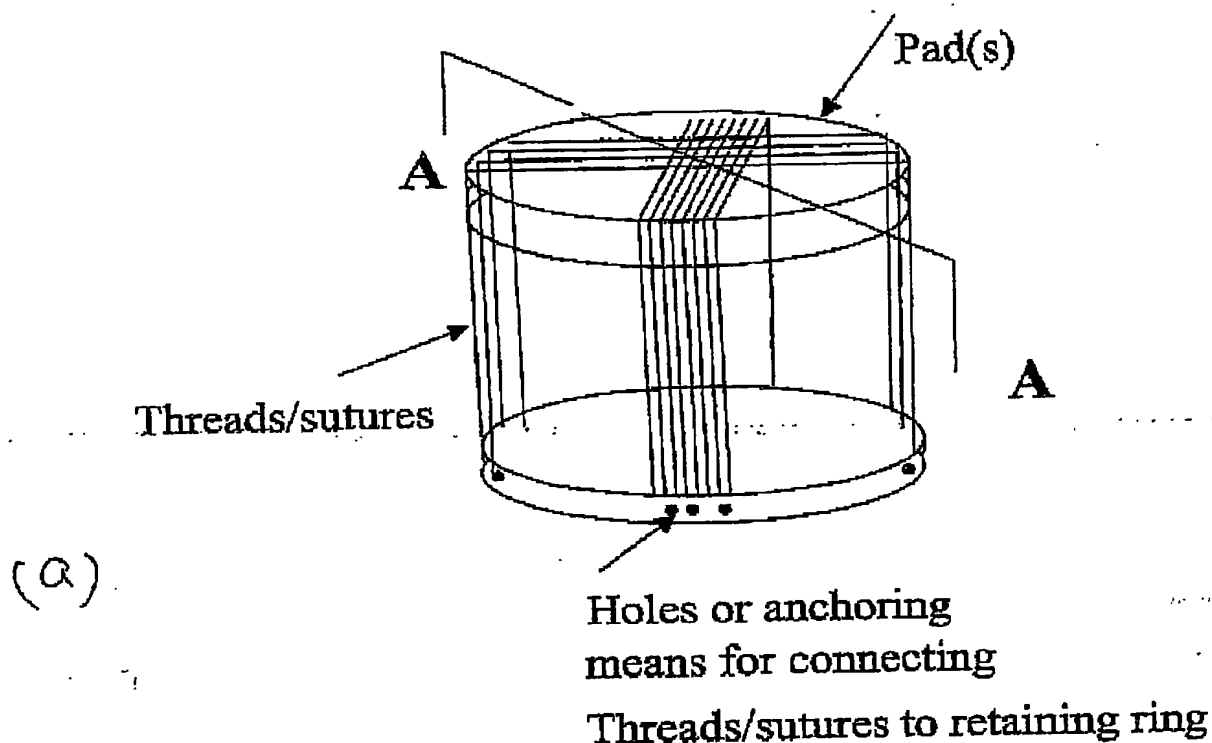


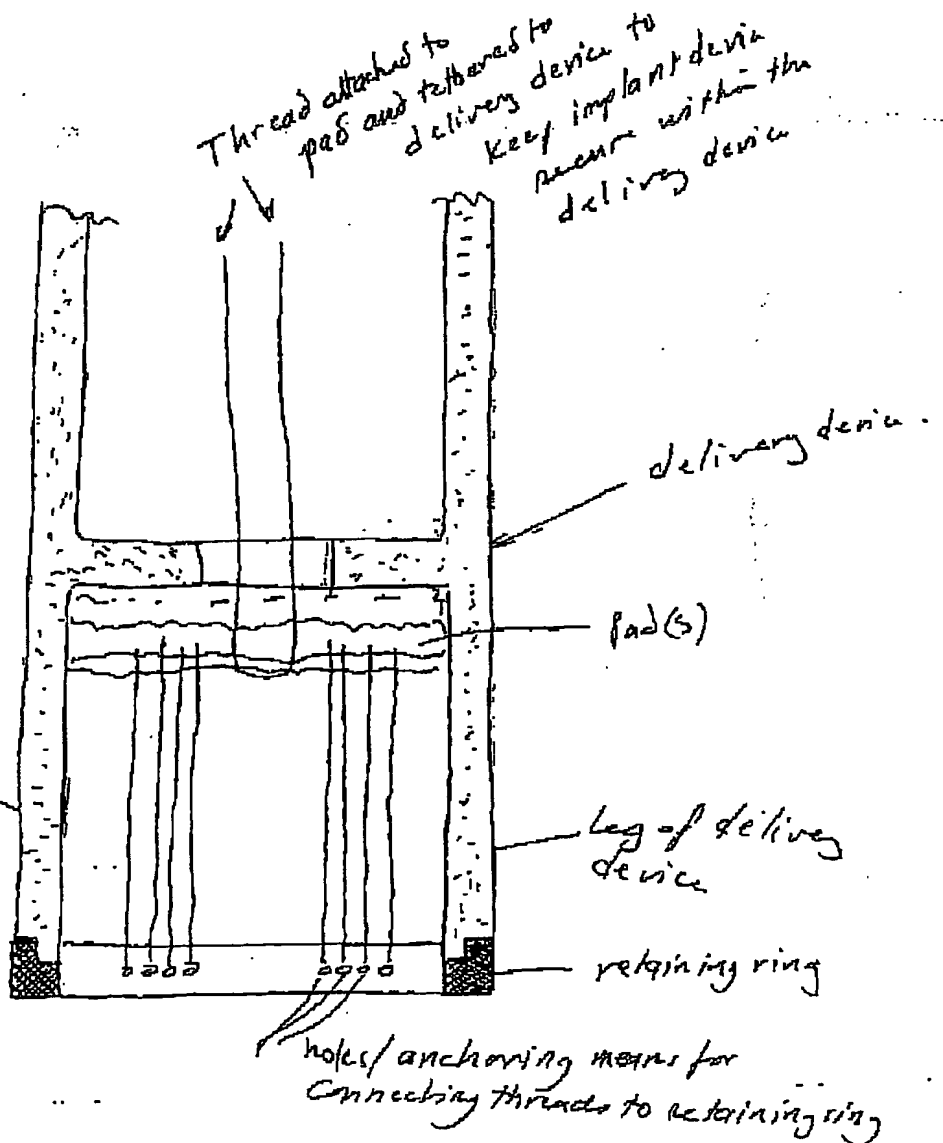
FIG. 10

~~Figure 7~~

10/10

FIG. 11FIG. 11

Leg of
delivery
device
engaging
step in
retaining
ring



Axial section through delivery device
and implant device

Figure 11

THE PATENT OFFICE
03 NOV 2004

PCT/GB2004/004536



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.